

REMARKS

Applicants respectfully request entry of amendments to claims 1, 26-29, 32-35, 38, 39, and 40-47, and cancel claims 30-31. Please withdraw claims 20-25, 36, and 37, without prejudice or disclaimer. Support for the amendments can be found throughout the specification, including paragraphs [0021], [0022], [0028], [0069], [0073], [0074], [0082], [0099], [0128], and [0138], and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 1, 26-29, 32-35, and 38-47 are in condition for allowance, and respectfully request that the claims as amended be entered.

Objections

Applicants have provided herewith a corrected claim 1 with reference to the language as suggested in the Office Action.

Applicants have provided herewith corrections to the subject matter of claims 1, 26, and 29. However, with respect to claims 30-39 and 45-47, Applicants traverse the objection because there has been no explanation provided which demonstrates that these claims contain any non-elected subject matter, except for the conclusory statement that they are drawn to such subject matter. Applicants can find no support in the previous Restriction Requirement of April 4, 2006 to explain how or why the Office Action has come to this conclusion. Further, with the exception of claims 30-31 (now canceled) and 36-37 (now withdrawn), the elements of the remaining claims simply define the components encoded by the claimed nucleic acid. Moreover, it is not clear to the Applicants how vectors and host cells are independent and distinct inventions from claims drawn to a nucleic acid. As such, Applicants submit that claims 30-35 and 45-47 do not contain non-elected subject matter.

For these reasons, Applicants respectfully request that the objections be withdrawn.

Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1, 26, 29-39, 41-43, and 45-47 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. As claims 30, 31, 36, and 37 have been canceled or withdrawn, the rejection as applied to these claims is rendered moot.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

Claim 1 no longer recites “reactive with at least one binding moiety or substrate” so the rejection is rendered moot. Applicants have amended the claim to recite “wherein domain 1 and domain 2 bind biotin.” The term “bind biotin” is a term of art and would be known to one of skill in the art generally as a property of streptavidin. These properties are recited at paragraphs [0022], [0028], as well as throughout the specification. As such, one of skill in the art would understand the metes and bounds of the term.

Regarding claims 29 and 31, while Applicants do not acquiesce to the reasoning offered in the Office Action, and to expedite prosecution toward allowance, claim 29 has been amended such that the elements are more clearly defined.

Regarding claim 34, the Office Action implies that the term “low complexity” is unclear, stating that “low” is relative and that there is no single set of conditions recognized by the art as being low. Applicants respectfully submit that this conclusion is incorrect.

For nucleic acids, “complexity is defined as the number of different sequences in DNA as defined by hybridization kinetics” (see, e.g., *Oxford Dictionary of Biochemistry and Molecular Biology*, Revised Ed., (Smith et al., eds.), 2001, Oxford University Press, New York, NY).

Further, the INCUBI Field Guide Glossary defines “Low Complexity,” as follows:

“Low Complexity Sequence

Low complexity sequence is a region of amino acid or nucleotide sequence with a biased residue composition. Low complexity sequence includes homopolymeric runs, short-period repeats, and some subtler over-representation of one or a few residues. Such sequences often look very redundant, for example the protein sequence PADPPPDPPPP or the nucleotide sequence AAATTTAAAAAT.”

(See, <<http://www.ncbi.nlm.nih.gov/Class/FieldGuide/glossary.html#I>>, last visited December 19, 2006). As such, the term is art recognized, and the skilled artisan would understand the metes and bounds of the term.

Regarding claim 47, while Applicants do not acquiesce to the reasoning offered in the Office Action, and to expedite prosecution toward allowance, claim 47 has been amended such that the elements are more clearly defined.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1, 26, 29-39, and 45-47 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description support. As claims 30, 31, 36, and 37 have been canceled or withdrawn, the rejection as applied to these claims is rendered moot.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that as the specification does not support that domain 1 and domain 2 “are reactive with at least one binding moiety or substrate,” including that the recited members of the Markush group in claim 26 are also not supported by the specification.

While not acquiescing to the reasoning offered in the Action, and to expedite prosecution towards allowance, Applicants have amended the claims such that the phrases at issues are no longer recited.

Regarding the linkers having low complexity, as stated in Fujikawa v. Wattanasin, 39 U.S.P.Q.2d, 1895 (Fed. Cir. 1996):

“*Ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.”

The specification clearly recites sequences which are short-period repeats, (see, e.g., the original claim 1, and paragraphs [0068], [0073], [0074], [0082], [0099], [0128], and [0138]).

Applicants submit that such short-period repeats represent “low complexity” linkers. Further, as this falls within the art recognized definition of “low complexity” (see above response to the indefiniteness rejection), Applicants submit that that such “low complexity” is inherent to the

original disclosure. Moreover, as stated in TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 60 U.S.P.Q 1017 (Fed. Cir. 2001):

“In order for a disclosure to be inherent, ‘the missing descriptive matter must necessarily be present in the [original] application’s specification such that one skilled in the art would recognize such a disclosure.’ Tronzo v. Biomet, Inc., 47 U.S.P.Q.2d 1829, 1834 (Fed. Cir. 1998).”

Thus, Applicants have met the standard for written description for the term “low complexity,” because one of skill in the art would recognize the disclosure of short-period repeats to represent “low complexity” linkers, and therefore, the addition of “low complexity” to the claims does not represent new matter.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 U.S.C. §103

Claims 1, 26, 29, 32, 37, and 45-47 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Botti et al. in view of Brown.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation in the references themselves or in knowledge generally available to one of skill in the art, to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. And, finally the prior art reference (or references when combined) must teach all claim limitations. The teaching or suggestion and reasonable expectation of success must both be found in the prior art and not in Applicants’ disclosure. (See M.P.E.P. §706.02(j)).

Applicants submit that because the cited references do not teach all the claim limitations, one of skill in the art would not be motivated to combine the reference teachings.

The Office Action alleges, in pertinent part, that Botti et al. is silent with respect to teaching that the metal binding domain of “GBP with sequence of SEQ ID NO:17.” The Action then provides Brown to cure the deficiency identified in the primary reference. The claims as

presently amended recite that “domain 1 and domain 2 are affinity binding proteins.” Review of the USPTO Class Definition for Class 530 – Chemistry: Natural Resins or Derivatives; Peptides or Proteins, defines “protein” as more than 100 amino acid residues (see subclass 350). Such fusion partners are described in the specification as Protein A, Protein G, streptavidin, and single chain antibodies (see, e.g., paragraph [0021]), all of which are polypeptides greater than 100 amino acids in length (see, e.g., SEQ ID NO:4 for Streptavidin-GBP-Streptavidin). Because a His6tag only comprises 3 or more amino acids joined covalently by peptide bonds, which defines a “peptide” (see subclass 300), not a protein, the His6tag would not fall under the definition of a “protein” as promulgated by the USPTO. Therefore, Applicants submit that as Botti et al. teach a metal binding protein comprising a His6tag moiety (i.e., less than 100 amino acid residues), they do not teach a fusion protein as claimed. Further, this deficiency is not cured by the teachings of Brown.

Because the teachings of Botti et al. would not result in a fusion protein as claimed when combined with the teachings of Brown, one of skill in the art would not have an expectation of success since the invention as claimed would not be achieved in view of such teachings. Therefore, one of skill in the art would not be motivated to combine such teachings.

Again, the “teaching or suggestion **and** reasonable expectation of success must **both** be found in the prior art.” (Emphasis added). One cannot simply use the Applicants’ disclosure as a “blueprint” to reconstruct, by hindsight, Applicants’ claim. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985). Because there is neither the suggestion nor expectation of success that can be found in the cited art, no *prima facie* case of obviousness has been established.

Applicants submit that because there is no motivation to combine the cited references, no *prima facie* case for obviousness exists. For these reasons, Applicants respectfully request that the rejection, including as it might be applied against the amended claims, be withdrawn.

In re Application of:
Woodbury et al.
Application No.: 10/671,995
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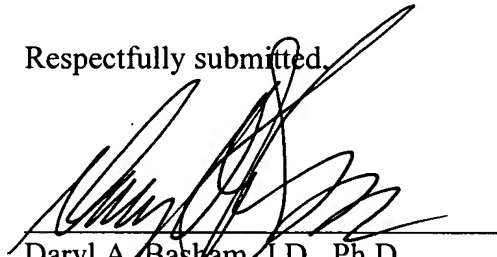
PATENT
Attorney Docket No. BIO1100

Conclusion

Applicants submit that pending claims 1, 26-29, 32-35, and 38-47 are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fee is deemed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees required by this submission, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,



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